REMARKS

By way of the present amendment, Claims 2 and 4-13 are pending. Claims 10-13 are withdrawn as being directed to a nonelected restriction group. No new matter is added by the present amendment.

I. Election/Restriction

Applicants acknowledge withdrawal by the Examiner of Claims 10-13. In withdrawing the claims, the Examiner asserts that "new claims 10-13 are drawn to transgenic plants/seeds, belonging to nonelected group III and are thus withdrawn from further consideration for being withdrawn to [a] nonelected invention, there being no allowable generic or linking claim." *Id.* Solely in order to facilitate prosecution, Applicants have withdrawn non-elected Claims 10-13 without prejudice to or disclaimer of the underlying subject matter. Applicants expressly reserve the right to rejoin non-elected species upon allowance of claims to the presently elected species.

II. Rejection under 35 U.S.C. § 101

Claims 2 and 4-9 stand rejected under 35 U.S.C. § 101, because allegedly the "claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility." Office Action at page 3. The Examiner further asserts that "[t]he claimed polypeptide is not supported by a specific and substantial asserted utility because none of the uses of the polypeptide as disclosed in the specification such as those detailed on pages 10-18, etc. is specific and substantial." *Id.* Applicants respectfully traverse this rejection.

In *In re Fisher*, the Federal Circuit reiterated that the "basic *quid pro quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived from the public from an invention with *substantial utility*." *In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005) (citing *Brenner v. Manson*, 383 U.S. at 534-35, 1966) (emphasis in original). The Court noted that since "*Brenner* our predecessor court, the Court of Customs and Patent Appeals, and this court have required a claimed invention to have a specific and substantial utility to satisfy § 101." *Id.* Furthermore, an invention need only provide one identifiable benefit to satisfy 35 U.S.C. § 101. *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958 (Fed. Cir. 1983) ("when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown").

Although the Supreme Court has not defined the meaning of the terms "specific" and "substantial", the Federal Circuit has identified a framework for the kind of disclosure an application could contain to establish a specific and substantial utility. *In re Fisher*, 421 F.3d at 1371. First, the Court indicated that to provide a substantial utility, the specification should disclose a utility such that "one skilled in the art can use a claimed discovery in a manner which provides some *immediate benefit to the public*." *Id.* (emphasis in original). Second, a specific utility can be disclosed by discussing "a use which is not so vague as to be meaningless," that is that the claimed invention "can be used to provide a well-defined and particular benefit to the public." *Id.*

There are numerous utilities asserted in the specification regarding SEQ ID NO: 44,293. Specification at page 19, line 12 - page 28, line 17 and Table 1. Additionally, the utility of SEQ ID NO: 44,293 is demonstrated by a BLASTP analysis. The specification as filed discloses that a

BLASTP analysis is a well-known and conventional technique that can be used to obtain information about nucleic acid sequences. Specification at page 15, line 16 - page 16, line 15. The results of a BLASTP analysis of SEQ ID NO: 44,293 show that SEQ ID NO: 44,293 correlates to a synaptobrevin 1 protein found in *Oryza sativa*. Applicants respectfully submit that the results of the BLASTP analysis demonstrate that SEQ ID NO: 44,293 has utilities specific to it and not generally applicable to any amino acid sequence. These utilities are credible, substantial, and well-established; they are neither vague nor impractical. Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and have done so in the present case.

A BLASTP analysis of SEQ ID NO: 44,293 is shown below and demonstrates that the claimed amino acid sequence strongly correlates (E-value=8e-107, where a "high" BLAST match is considered as having an E-value as less than 1E-30) to an amino acid sequence having utility as a synaptobrevin 1 protein found in *Oryza sativa*. Applicants have provided the parameters for the above-described BLASTP analysis in the accompanying Information Disclosure Statement. The BLASTP search reveals that SEQ ID NO: 44,293 is 96% identical to a synaptobrevin 1 protein found in *Oryza sativa*. Alone, this is sufficient to satisfy the utility requirement under 35 U.S.C. § 101.

>ref|NP_001059109.1| UG Os07g0194000 [Oryza sativa (japonica cultivar-group)]
dbj|BAD30158.1| G synaptobrevin-like protein [Oryza sativa Japonica Group]
emb|CAD70274.1| G synaptobrevin 1 [Oryza sativa (japonica cultivar-group)]
dbj|BAF21023.1| G Os07g0194000 [Oryza sativa (japonica cultivar-group)]
Length=220

GENE ID: 4342638 Os07g0194000 | Os07g0194000 [Oryza sativa Japonica Group]
(10 or fewer PubMed links)

Score = 389 bits (999), Expect = 8e-107, Method: Compositional matrix adjust.
Identities = 212/219 (96%), Positives = 217/219 (99%), Gaps = 0/219 (0%)

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Query  1    MGQQSLIYAFVARGTVILAEYTEFTGNFTTIASQCLMKLPASNNKFTYNCDGHTFNYLVE  60
            MGQQSLIYAFVARGTV+LAEYTEFTGNFTTIA+QCL KLPASNNKFTYNCDGHTFNYLVE
Sbjct  1    MGQQSLIYAFVARGTVVLAEYTEFTGNFTTIAAQCLQKLPASNNKFTYNCDGHTFNYLVE  60

Query  61   DGFTYCVVAVESVGQQIPIAFMDRVKEDFTKRYGGGKAATAAANSLNREFGSKLKEHMQY  120
            DGFTYCVVAVESVG+QIPIAF+DRVKEDFTKRYGGGKAATAAANSLNREFGSKLKEHMQY
Sbjct  61   DGFTYCVVAVESVGRQIPIAFLDRVKEDFTKRYGGGKAATAAANSLNREFGSKLKEHMQY  120

Query  121  CVDHPEEVSKLAKVKAQVSEVKGVMMENIEKVLDRGEKIELLVDKTENLRSQADFRQQG  180
            CVDHPEE+SKLAKVKAQVSEVKGVMMENIEKVLDRGEKIELLVDKTENLRSQADFRQQG
Sbjct  121  CVDHPEEISKLAKVKAQVSEVKGVMMENIEKVLDRGEKIELLVDKTENLRSQADFRQQG  180

Query  181  TNVRRKMWLQNMKIKLIVLGIIIALILIIIILSVCHGFKC  219
            T VRRKMWLQNMKIKLIVLGIIIALILIIIILSVCHGFKC
Sbjct  181  TKVRRKMWLQNMKIKLIVLGIIIALILIIIILSVCHGFKC  219
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Moreover, Table 1 indicates that SEQ ID NO: 44,293 exhibits a strong correlation to a synaptobrevin-like protein, gi29150380. According to Table 1, SEQ ID NO: 44,293 shares 96% identity with gi29150380. However, the Examiner ignores the high similarity between these two proteins when maintaining the rejections and concludes that "sequence similarity alone does not reliably correlate to identical or even similar biological activities." Office Action at page 5.

Applicants dispute the Examiner's reliance on Everett *et al.* (Nature Genetics 17, 411-422 (1997)) and Scott *et al.* (Nature Genetics 21, 440-443 (1999)) to allegedly show that "assignment of a known function to a metabolic gene based on homology alone provides improper and erroneous functional assignment." Office Action at page 6. Citing to Everett *et al.* and Scott *et al.*, the Examiner further asserts that sequence similarity alone does not correlate to identical or even similar biological activities. *Id.* at page 5. As alleged evidence of this, the Examiner cites to Scott *et al.* and states that "pendrin, while having 29% homology to the rate sulfate-ion transporter encoded by *Sat*-1; 32% homology to the diastrophic dysplasia sulfate transporter *DTD*; and 45% homology to the human sulfate transporter down-regulated adenoma encoded by *DRA*, is actually not a transporter of sulfate, but rather that of chloride and iodine." *Id.*

The above-mentioned findings by Scott *et al.* and Everett *et al.* have no bearing whatsoever on the utility of SEQ ID NO: 44,293. For one, Scott *et al.* compares the biological activity of pendrin to sulfate transporters with only 29%, 32%, and 45% structural identity to pendrin. Scott *et al.* at abstract. Everett *et al.* does not remedy the deficiency of Scott *et al.* and compares the biological activity of pendrin to sulfate transporters with only 29%, 31%, 32%, and 45% structural identity to pendrin. Everett *et al.* at Figure 4. Here, SEQ ID NO: 44,293 shares a 96% identity to a known synaptobrevin 1 protein found in *Oryza sativa*. This is much higher than the percent identities of only 29%, 31%, 32%, and 45% stated in Scott *et al.* and Everett *et al.* With this, one of skill in the art would be comfortable that proteins sharing 96% identity would share the same biological function as compared to proteins sharing only 29%, 31%, 32%, or 45% identity. Additionally, the Examiner does not provide any support for the apparent proposition that a single example of an alleged improper functional assignment based on homology to a known sequence renders homology-based functional assignments unreasonable generally, and in the present case specifically.

Moreover, Applicants strongly disagree with the Examiner's position that the Scott *et al.* and Everett *et al.* references confirm that structural homology is not an accurate predictor of function. Office Action at page 5. In fact, Scott *et al.* actually confirms that even a very low percentage of structural identity can be indicative of similar biological function. Specifically, according to Scott *et al.*, transporters sharing only 29%, 32%, and 45% structural identity to pendrin still have the ability the ability to act as **anion transporters**. That is, like pendrin, which is a sulfate-anion transporter, transporters sharing only 29%, 32%, and 45% structural identity to

pendrin have the ability to transport iodide and chloride, both anions. Scott *et al.* at abstract and Figure 2. However, the Examiner ignores this point in rejecting Applicants' claims.

The present application provides utilities for the claimed polypeptides that are well-defined and provide an immediate benefit to the public. The fact that the claimed amino acid sequence exhibits a high correlation to a synaptobrevin 1 protein is more than ample to support the specific utilities asserted in the specification for SEQ ID NO: 44,293. Additionally, the specification provides that the sequences of the invention can be used for monitoring and modifying synaptobrevin-like protein expression in plants. Specification at page 25, line 6 through page 28, line 17 and Table 1. The specification discloses that nucleic acid sequences encoding the synaptobrevin-like protein can be introduced into a plant cell and transcribed using an appropriate promoter with such transcription resulting in the reduction or suppression of the endogenous synaptobrevin-like protein. Specification at page 19, line 12 through page 28, line 17. The modification of the expression can be monitored, for example, by using an ELISA assay to raise specific antibodies to either a synaptobrevin 1 or synaptobrevin-like protein. Specification at page 25, line 16 through page 26, line 18. Such antibodies can be prepared using the claimed polypeptide sequences. Any one of these asserted utilities is specific, substantial and credible under the requirements of 35 U.S.C. § 101.

Applicants respectfully remind the Examiner that the utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). As the law provides, "a 'rigorous correlation' need not be shown in order to establish practical utility; 'reasonable correlation' is sufficient." *See, Fujikawa v. Wattanasin*, 93 F.3d

1559, 1565, 39 U.S.P.Q.2d 1895, 1900 (Fed. Cir. 1996), emphasis added. "An Applicant can establish this reasonable correlation by relying on statistically relevant data documenting the activity of the compound or composition, arguments or reasoning, documentary evidence, or any combination thereof." M.P.E.P. § 2107.03, at page 2100-43. By providing a BLASTP analysis, Applicants have submitted a reasonable correlation of SEQ ID NO: 44,293 to synaptobrevin 1 and synaptobrevin-like proteins to support the specific, substantial and credible utilities asserted for SEQ ID NO: 44,293. Moreover, the E-value of 8e-107 for the translated protein of the claimed sequence is a reasonable correlation.

In rejecting the claims, the Examiner further asserts that "assuming *arguendo* that the polypeptide of SEQ ID NO: 44293 were indeed a synaptobrevin-like protein, one skilled in the art would have to perform further research to determine how much activity is 'like' synaptobrevin, and what specific and substantial utility the protein might have." Office Action at page 6. The Examiner further cites to Raptis *et al.* (Journal of Chemical Neuroanatomy, Vol. 30, pages 201-211, 2005) and asserts that this reference discloses at least two isoforms of synaptobrevins: synaptobrevin/VAMP 1 and synaptobrevin/VAMP 2. *Id.* at page 7.

Applicants respectfully dispute the Examiner's reliance on Raptis *et al.* to allegedly show that SEQ ID NO: 44293 lacks utility under 35 U.S.C. § 101. For one, the BLASTP search reveals that SEQ ID NO: 44,293 is 96% identical to a **synaptobrevin 1** protein found in *Oryza sativa*. This finding renders the Examiner's concern about the multiple isoforms of synaptobrevins moot. Moreover, Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and have done so in the present case. As such, one of ordinary skill in the art

would recognize that the claimed amino acid sequence has utility, and the asserted utilities are immediately apparent without further research.

Applicants respectfully submit that they have satisfied the utility test set forth in *In re Fisher*. SEQ ID NO: 44,293 is reasonably (*i.e.*, E-value = 8e-107) correlated to synaptobrevin 1 and synaptobrevin-like proteins, therefore, the claimed invention has specific, substantial, credible, and well-established utilities. In conclusion, Applicants respectfully submit that SEQ ID NO: 44,293 has specific, substantial, and credible utility because it has a reasonable correlation with both synaptobrevin 1 and synaptobrevin-like proteins, and can be used in a manner that provides some immediate benefit to the public. Therefore, Applicants respectfully request that the Examiner reverse the rejection of claims 2 and 4-9 under 35 U.S.C. § 101.

III. Rejection Under 35 U.S.C. § 112, First Paragraph, Enablement

Claims 2 and 4-9 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly not being enabled because the claimed invention allegedly lacks utility. Office Action at page 8. Applicants respectfully traverse this rejection and submit that this rejection has been overcome by the arguments set forth above regarding utility. Thus, the enablement rejection under 35 U.S.C. § 112, first paragraph is improper. Applicants respectfully request reconsideration and withdrawal of this ground of rejection.

IV. Claim Rejections under 35 U.S.C. § 102:

Claims 2 and 4-9 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Alexandrov *et al.* (EP 1 033 405). Office Action at page 8. Applicants respectfully traverse.

In rejecting the claims, the Office asserts that "[t]he rejection is newly added, which is necessitated by the amendments filed 11/26/07." Office Action at page 9. Applicants

respectfully dispute this assertion. For one, the Office previously cited Alexandrov *et al.* against the claims in the January 25, 2007 Final Office Action at page 15, but subsequently withdrew these rejections in the Advisory Action mailed September 6, 2007 in response to Applicants' arguments in the May 25, 2007 response.

Moreover, Applicants note that Alexandrov *et al.* is not prior art against the claims. As set forth in the May 25, 2007 response, Alexandrov *et al.* can not be prior art to the claimed invention, which claims priority at least to May 6, 1999. *See*, Application Data Sheet, filed May 25, 2007. That is, Alexandrov *et al.*, with a filing date of February 25, 2000, was not patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for patent in the United States. 35 U.S.C. § 102(b). Therefore, consistent with the Office's assessment in the Advisory Action mailed September 6, 2007, Applicants respectfully request withdrawal of this rejection.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully submit that the present application is now in condition for allowance, and respectfully request notice of such. The Examiner is encouraged to contact the undersigned at 202-942-5325 if any additional information is necessary for allowance.

Respectfully submitted,

Date: May 14, 2008

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